



APPLICATION 10/634,869

Information Disclosure Statement

Copies of documents presented for consideration are listed on a separate form, but also are noted below with “extras” -- commentary and directions -- to direct the reviewer. These documents refer to three epidemiology (human) data sets: [A] the Taiwan data set, part of which the EPA regulators relied on in lowering the arsenic in drinking water standard from 50 to 10 $\mu\text{g/L}$ (or parts per billion [ppb]); [B] the Millard, Utah data set that EPA scientists collected and published on, but EPA regulators ignored; and [C] the Cuzak data set of British patients treated medicinally for non cancer ills with arsenic.

A.

1. Kayajanian, G. “Arsenic, cancer and thoughtless policy” (2003). Ecotoxicology and Environmental Science 55: 139-142. This paper examines broad cancer groupings in all three data sets.
2. Pages 308-309 [Table A-10-1] NRC (NAS) 1999 Arsenic in Drinking Water Report. National Academy Press. These two pages contain the actual data EPA employed to justify lowering the arsenic standard; Kayajanian also relied on this table to contradict the EPA claims and, in part, to make his patent claims.
3. Morales, KH, Ryan, L et al., “Risk of Internal Cancers from Arsenic in Drinking Water” (2000). Environmental Health Perspectives 108(7): 655-661. This paper draws the EPA conclusion that lowering the arsenic level always lowers the bladder cancer mortality. Note particularly in Table 5 the Cancer and PYR (person-years) entries associated with exposure categories 0-50 and 50-100. The cancer rate increases in 0-50 compared to 50-100, which Morales, Ryan fail to note, even as they validate the kind of comparison Kayajanian makes using exposure groupings [(10-32) and (42-60)], which are more relevant to the EPA regulatory question: Should EPA keep the arsenic-in-drinking-water standard at 50 ppb or lower it?

B.

4. Cover sheet (identity of sender deleted), two tables, five-page 2000 EPA Report [“A Re-Analysis of Arsenic-Related Bladder and Lung Cancer Mortality in Millard County, Utah”] and 55-page data set on the Millard, Utah population published on by Lewis, Southwick et al. in 1999.
5. Manuscript: Kayajanian, G. “J-shaped Disease Response to Arsenic Levels in Utah Drinking Water” based on the 55-page Millard, Utah set, drafted prior to this patent filing.

C.

6. Cuzick, J., Evans, S. et al. “Medicinal Arsenic and Internal Malignancies” (1982). British Journal Cancer 45: 904-910. See Table III.

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PTO/SB/08a (07-05)

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

one

of

2

Complete if Known

Application Number

10/634,869

Filing Date

816/2003

First Named Inventor

Кацарский Г.

Art Unit

1694

Examiner Name

JAMES D. Anderson

Attorney Docket Number

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/634,869
Filing Date	8/6/2003
First Named Inventor	KAYAJANIAN, G
Art Unit	1614
Examiner Name	James D. Anderson
Attorney Docket Number	

Sheet two of 2**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		KAYAJANIAN, G. "Arsenic cancer and thoughtless policy (2003) Ecotoxicology & Environmental Safety 55: 139-142, USA	
		PP 308-309 NAS/NRC Report on Arsenic in Drinking Water (TABLE LO-IA) (1999) NATIONAL ACADEMY PRESS	
		Morales, KH, Ryan L, et al. Risk of Internal Cancers from Arsenic in Drinking Water (2000) Env. Health Perspectives 108(7): 655-661.	
		EPA Report (2000) "A Re-Analysis of Arsenic-Related Bladder and Lung Cancer Mortality in Millard County, Utah - 5 pages plus 2 pages of graphs plus 55 page dataset } unpublished { plus cover letter	
		Manuscript: Kayajanian, G. "J-shaped disease response to Arsenic levels in Utah drinking water - 13 pages (2003)	
		Cuzick, J., Evans, S. et al (1982) "Medicinal Arsenic and Internal Malignancies" British Journal Cancer. 45: 904-910	
		1 page Information Disclosure Statement	
		1 page Specifications	
		2 page Application of Specifications	
		1 page Claim Rejection comments/Response	
		1 page Correspondence and meeting records	

Examiner
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